

## **REMARKS**

### **Amendments**

New claim 30 is an independent claim similar to claim 1 except that Q is defined as an unbranched, unsubstituted alkylene chain having 1 to 2 carbon atoms. See, e.g., page 7 of applicant's specification.

### **Obviousness-Type Double Patenting Rejection**

Claims 1-3, 5,6, 8-11, and 14-29 are rejected on grounds of obviousness-type double patenting in view of claims 1-15 of Steinmeyer et al. (US 5,585,368) and claims 1-9 of Steinmeyer et al. (US 5,700,791). US '791 is a Divisional of US '368. This rejection is respectfully traversed.

The rejection fails to state any reasons as to why the claimed subject matter is considered to be obvious in view of the claims of US '368 or US '791. In the rejection, it is merely asserted that the instantly claimed subject matter is "fully disclosed in the patent and is covered by the patent." Thereafter, it is stated that the claimed invention "is drawn to the vitamin D derivatives which are considered obvious over the claims of the prior U.S. patent issued to the same inventor and same assignee." These statements merely present an unsupported conclusion of obviousness. No rationale is presented as to why they are considered obvious. Moreover, nothing within the rejection speaks to the requisite motivation that would lead one of ordinary skill in the art to a compound in accordance with the claimed invention. For these reasons alone, the obviousness-type double patenting rejection should be withdrawn.

In claim 1 of US '368, group Z is defined as H, OH or alkanoyloxy group having 1-9 carbon atoms. Group L is defined as  $-\text{CH}_2\text{-A-B-}$  in which A is O and B is  $-(\text{CH}_2)_n-$  with n being 1-6. Alternatively, L can be  $-\text{D-CHE-CHF-G-}$  in which D is a direct bond, a methylene bridge or a 1,2 ethenediyl bridge between carbon atoms 20 and 22. E and F are each hydrogen atom or together form a second bond. G is a direct bond or is  $-(\text{CH}_2)_n-$  with n being 1-6 and in which a  $-\text{CH}_2-$  group can be replaced by a oxygen atom. As for US '791, the descriptions of groups L and D in the claims thereof are the same as in US '368.

Conversely, in applicants claim 1 there is a structure  $-\text{CHV-CHW-Q-}$  in which V and W are a double bond or V is hydroxyl and W is hydrogen. Q is defined as a carbon unit having up to 10 carbon atoms which have can have alpha or beta hydroxy groups, amino

groups, and/or halogen atoms and wherein the mentioned hydroxy groups can be esterified or etherified. In addition, group Z is defined as a saturated or unsaturated hydrocarbon radical having up to 12 C atoms. This group can have keto groups, alpha or beta hydroxyl groups, amino groups, chlorine, and/or bromine atoms, in which the hydroxyl substituents can be esterified or etherified.

With respect to the double patenting rejection, it is the claims in the reference which are to be relied on, not the disclosure in the specification. Nothing within the claims of US '368 and/or US' 791 provides any suggestion or motivation for modifying the compounds described therein in such a manner as to arrive at a compound in accordance with applicants' claim 1. In view of the above remarks, it is respectfully submitted that neither the claims of US '368 nor the claims of US '791 render obvious applicants' claimed invention. Withdrawal of the obviousness-type double patenting rejection is respectfully requested.

**Rejection Under 35 U.S.C. §102(b) In View of Kirsh et al. (WO 97/00242)**

Claims 1 and 4 are rejected under 35 U.S.C. §102(b) as being anticipated in view of Kirsch et al. (WO '242). This rejection is respectfully traversed.

This rejection was previously presented in the Office Action of September 13, 2000. Applicants traversed the rejection in the Amendment of March 12, 2001. The Office Action of June 4, 2001 does not respond to the arguments presented in the March 12, 2001 Amendment. Applicants again traversed this rejection for the reasons of record. The arguments from the March 12, 2001 Amendment are presented below.

Applicants' wish to inform the Examiner that there is a U.S. National Phase corresponding to WO '242, i.e., Serial No. 08/981,819 (filing date March 31, 1998). A Notice of Allowance and Issue Fee due was issued in Serial No. '819 on December 12, 2000. A continuation application of Serial No. '819 was filed on December 18, 2000, i.e., Serial No. 09/738,286, which is still pending.

In the rejection, reference is made to compounds 106a and 106b at page 2 of WO '242 and Example XXXIV at page 36. It is stated in the rejection that these compounds exhibit a cyclopropyl group at the C-25 position.

Compounds 106a and 106b, in addition to exhibiting the cyclopropyl group at the C-25 position, exhibit a keto group at the C-24 position. Also, Group Z, which is attached to the C-25 position, is  $\text{CHOH-C}_4\text{F}_9$ .

The compound of formula XXXIV at page 36 also exhibits a cyclopropyl group at the C-25 position and at the C-24 position exhibits the group CHOR<sub>11</sub>. In addition, Group Z' is attached to the C-25 position. R<sub>11</sub> is an acid-labile protective group having a definition analogous to Y'<sub>1</sub> or Y'<sub>2</sub>, or is tetrahydropyranyl, tetrahydrofuranyl, ethoxyethyl, methoxymethyl, or methoxyethoxyethyl. See the disclosure at the middle of page 27. Y'<sub>1</sub> is a hydrogen atom or a protective hydroxy group and Y'<sub>2</sub> is a hydroxy protective group. See the description of Y'<sub>1</sub> and Y'<sub>2</sub> at page 22 immediately following formula II. Z' is analogous to group Z of WO '242 or optionally exhibits protective group-carrying substituents. See the bottom of page 22.

Compounds 106a, 106b and the compound of Example XXXIV of WO '242 fail to anticipate applicants' claim 1. See the "wherein" clause at the end of claim 1, which further defines Group Q (the C-24 position). See also the description of group Z which is attached to the C-25 position. Withdrawal of the rejection under 35 U.S.C. §102(b) is respectfully requested.

#### **Rejection Under 35 U.S.C. §103 In View of Kirsch et al. (WO '242)**

Claims 14-29 are rejected as being obvious in view of Kirsch et al. This rejection is respectfully traversed.

Firstly, applicants' request clarification as to which claims are being rejected under 35 USC §103. The rejection states that "Claims and new claims 14-29 are rejected under 35 U.S.C. §103(a)." Thus, aside from claims 14-29, it is unclear which other claims are rejected on this ground.

This rejection is also repeated from the Office Action of September 12, 2000. Applicants traversed the rejection in the March 12, 2001 Amendment. The recent Office Action does not respond to Applicants' arguments, which are reproduced below.

In the rejection, reference is made to formula I at page 1 and Example XXXIV at page 36. Further, it is argued that WO '242 discloses 3-7 numbered carbocyclic or heterocyclic ring groups at the C-25 position.

In formula I of WO '242, the C-24 position is substituted by Groups A and B. Groups A and B can together form a keto group. Alternatively, Group A can be OR' and B can be a hydrogen atom or B can be OR' and A can be a hydrogen atom. R' is a hydrogen atom, an alkanoyl group of up to 9 carbon atoms, or an aroyl group.

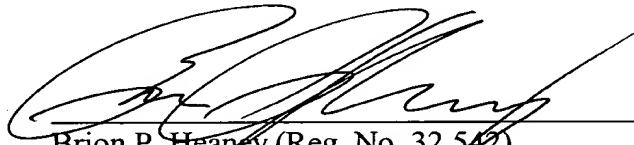
In the §102(b) rejection, only three specific compounds of WO '242 are mentioned. In compounds 106a and 106b, the C-24 position is substituted by a keto group. In the compound of Example XXXIV, the C-24 position is CHOR<sub>11</sub>. The disclosure of WO '242 describes a broad genus of compounds. Within the genus, the substituent at the C-25 position is not specifically a cyclopropyl ring, but is instead a broader class of substituents as is acknowledged in rejection.

One of ordinary skill in the art presented with the disclosure of WO '242 and its broad genus of compound is not provided with sufficient motivation to modify the compounds therein, or particularly compounds 106a, 106b and the compound of formula XXXIV, in such a manner as to arrive at a compound in accordance with applicants' claims genus. The mere disclosure of a broad genus of compounds does not, in and of itself, establish obviousness with respect to each and every compound encompassed therein. See, for example, *In re Jones*, 21 USPQ 2d 1941 (Fed. Cir. 1991) and *In re Baird*, 29 USPQ 2d 1550 (Fed. Cir. 1994). Instead, the disclosure must provide some motivation which would lead one of ordinary skill in the art, without the benefit of hindsight, to modify the disclosed compounds in such a manner as to arrive at the claimed compound.

In this case, no such motivation is presented in WO '242 or is asserted in the rejection that would lead one of ordinary skill in the art to modify the C-25 cyclopropyl compounds disclosed in WO '242 in such a manner as to arrive at a compound in accordance with applicants' claimed genus. This is particularly the case for the compound of formula XXXIV which is described in WO '242 as an intermediate within a synthesis process. There is no motivation to interrupt the synthesis process, isolate the intermediate, and modify its structure. See, e.g., *In re Lalu et al.*, 223 USPQ 1257 (Fed. Cir. 1984).

In view of the above remarks, it is respectfully submitted that Kirsch et al. (WO '242) fails to provide sufficient motivation to render obvious applicants' claimed invention. Withdrawal the rejection under 35 U.S.C. §103 is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Brion P. Heaney', is written over a horizontal line.

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